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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/600,947 | 07/25/2000 | BRUCE TOWE | A31178PCTA | 4172 |

7590 04/16/2002

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[REDACTED] EXAMINER

ALEXANDER, LYLE

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1743

DATE MAILED: 04/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/600,947 | TOWE, BRUCE |
| | Examiner | Art Unit |
| | Lyle A Alexander | 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-19 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite as to what is the "sensing substance" (e.g. what characteristics does it sense ?).

Claim 11 is confusing what structure is intended by "collapsible bag".

Claim 12 is confusing how an "optical cell" can further limit the thermopile sensor of claim 1. A reference that reads on claim 1 (e.g. containing a thermopile) will not be applicable to the optical cell limitations of claims 12-19. For the purposes of examination, it will be assumed claim 12 is an independent claim and does not contain the limitation of a thermopile.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Guilbeau et al.

Guilbeau et al. teach a systems for the determination of glucose in blood by the reaction of the blood with the enzyme glucose oxidase. The reaction occurs in a hollow membrane and the temperature of the reaction is monitored. Increases in temperature

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are proportional to the glucose in the sample. Column 5 lines 5-18 teach the thermopile is composed of a plurality of junctions. Column 5 lines 58-62 teach a standard curve created by using known concentration of glucose which has been read on the claimed glucose calibration compound.

Claims 12-16 and 18-19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burgess.

In light of the 35 USC 112 second paragraph issues noted above, for the purposes of examination claim 12 will be treated as though it were an independent claim.

Burgess teaches a system for the detection of an analyte using a reagent that reacts with the analyte. Column 3 lines 45-50 teach the reaction may emit visible light (read on the claimed color change). Column 6 lines 65 thought column 7 teach the reaction may be a fluorescent emission. Column 4 lines 18-20 teach the use of a sweep fluid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Guilbeau et al.alone or in view of Williams.

See Guilbeau et al.supra.

Guilbeau et al. are silent to the claimed polymers used to construct the device.

The court decided In re Leshin (125 USPQ 416) that mere selection of a plastic based upon its suitability of intended use would have been obvious. It would have been within the skill of the art to modify Guilbeau et al. and use polymers, such as acetate, polysulfone, polyacrylonitrile, cellulose and mixtures thereof in view of Leshin.

Williams teaches a similar device for the determination of glucose concentration by the monitoring the temperature with a thermocouple of the subsequent reaction with glucose oxidase. Williams teaches in column 6 lines 41-47 that cellulose is a suitable material of construction because it is selectively permeable to blood constituents of lower molecular weight, such as glucose.

It would have been within the skill of the art to modify Guilbeau et al. in view of Williams and use a known and convention material of construction, such as acetate, to gain the above advantages.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess.

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See Burgess supra.

Burgess is silent to the type of fluid used as the sweep fluid .

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has predictable and well known results. When choosing a sweep fluid one would choose a fluid that would not react with the analytes of interest. Both water and saline are known, inexpensive and readily available fluids that would not react with the analyte of interest or harm the host upon which the test are performed. It would have been within the skill of the art to modify Burgess and use water or saline as the sweep fluids to gain the above advantages and/or optimization of a result effective variable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 703-308-3893. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 703-308-4037 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0651.


Lyle A Alexander
Primary Examiner
Art Unit 1743

April 12, 2002